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DEPARTMENT OF THE ARMY OFFICE OF THE SURGEON GENERAL WASHINGTON, D.C. 20310



SGRD-HR

29 March 1979

SUBJECT:

Minutes of Ad Hoc Subcommittee of The Surgeon General's Human Use Review Committee Meeting -26 March 1979

The Surgeon General Headquarters, Department of the Army Washington, DC 20310

1. Under the provisions of AR 70-25 and OTSG Reg 15-2, a special meeting of an Ad Hoc Subcommittee of the Human Subjects Research Review Board (HSRRB) was convened at 1100 hours in Room 2E465 in the Pentagon on 26 March 1979 to consider human use issues of protocols presented by Stanford Research Institute (SRI) [TDSIILADREVGPL (U) - 23 March 1979] and the Army Materiel System Analysis Activity (AMSAA) [PDAAADREVGPL (U) - 23 March 1979].

a. Members present were:

- COL Edward L. Buescher, MC, Chairman, HSRRB.
- COL Harry Holloway, MC, Professor and Chairman, Department of Psychiatry, USUHS, Ad Hoc Member, HSRRB.
- Dr. K. E. Emerson, PhD, Consultant Ad Hoc Member, HSRRB.
- Dr. Herbert L. Ley, M.D., Consultant Ad Hoc Member, HSRRB.
- Dr. Chris J. D. Zarafonetis, M.D., Consultant Ad Hoc Member, HSRRB.
- Ms Annie L. Young, Systems Analyst, AMSAA, Ad Hoc Member, HSRRB.
- MAJ Frank Arness, JAGC, Judge Advocate, USAMRDC, and Member, HSRRB.
- MAJ Richard W. Severson, MSC, C, HURO, Recorder for HSRRB.

b. Also present were:

- Dr. Hal Puthoff, PhD, Stanford Research Institute, Menlo Park, CA.
- Mr. Russell Targ, Stanford Research Institute, Menlo Park, CA.
- -Mr. John Kramar, Assistant Director, Army Materiel Systems Analysis Activity, Aberdeen Proving Ground, MD.
 - COL Garrison Rapmund, MC, Director, Walter Reed Army Institute of Research, Washington, DC.

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- 2. Mr. Targ and Dr. Puthoff presented the SRI protocol to the Ad Hoc Subcommittee. Mr. Kramar presented the AMSAA protocol. Subsequent to discussions, the following is the unanimous consensus of the Subcommittee members:
- * a. The Stanford Research Institute protocol was identified as technology transfer rather than research or testing. Similarly, the Army Materiel System Analysis Activity protocol was judged to be phenomenological validation of the technology to be transferred by SRI. Descriptions of procedures and modes of evaluation are straightforward and do not present any known hazard to the persons involved.
- b. For reasons stated above, Federal guidelines and Army regulations on the use of human subjects do not apply.
- 3. While the Ad Hoc Subcommittee judged the current protocols as other than research or clinical investigations involving human subjects, sometime in the future it is possible that follow-on work may be categorized as research, and may involve human subjects. If any follow-on research should involve human subjects, the Ad Hoc Subcommittee felt that the Army sponsors and action agencies are presently unprepared to address all anticipated problems. Specifically, the concerns include:
- a. Provision for adequate scientific review of research protocols.
- b. Provision for collaborating behavioral scientists in execution of protocols.
- c. Provision for credible Human Use Review processes or committees in action agencies for review of protocols.
- 4. The Ad Hoc Subcommittee recommended that the Army sponsors and action agencies make plans to provide for solutions to the deficiencies listed in paragraph 3, above, in the event that follow-on work is planned.

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5. There being no further business, the meeting was adjourned at 1550 hours.

RICHARD W. SEVERSON

MAJ, MSC Recorder

APPROVED/BISAPPROVED:

APPROVED/DISAPPROVED:

EDWARD L. BUESCHER

Colonel, MC

Chairman, Human Subjects

Research Review Board

CHARLES C PIVIEN

Lieutenant General

The Surgeon General